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DK

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/141,220      | 08/27/98    | BANNON               | HS-102              |

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HM12/0411

EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/141,220**

Applicant(s)

**Bannon**

Examiner

**DeCloux, Amy**

Group Art Unit

**1644**



☒ Responsive to communication(s) filed on Jul 26, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-36 is/are pending in the application.

Of the above, claim(s) 14-36 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-36 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with Sequence Requirements

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

#### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed as described in the last paragraph of this office action.

2. Applicant's election with traverse of Group I, Claims 1-13 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Group I, drawn to a method of making a modified allergen, and Group II drawn to a modified allergen, should be examined as one group since the claims are related as a process for making and product of the process. This is not found persuasive because of the reasons of record in the restriction requirement filed 6/22/99. Inventions I and II and are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the outcomes, as stated in the restriction requirement filed 6/22/99.

The requirement is still deemed proper and is therefore made final. Accordingly, claims 14-36 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Sequences are disclosed in the instant specification (see pages 22, 23, 26, And 27 for example). Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37

C.F.R. 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

5. Claim 8 is objected to because of the following informalities: There should be a hyphen between IL and 12, IL and 16, and IL and 18, and all three letters in lfn should be capitalized.

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of copending Application No. 09/248,674 and as that of claim 7 of copending Application No. 09/248,673 and as that of claim 12 of copending Application No. 09/240,577. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 12 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 8 of copending Application No. 09/248,674 and as that of claim 8 of copending Application No. 09/248,673. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

8. Claim 1 is directed to the same invention as that of claim 7 of commonly assigned application number 09/248,674 and claim 7 of commonly assigned application number 09/248,673 and claim 12 of commonly assigned application number 09/240,674. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Claim 12 is directed to the same invention as that of claim 8 of commonly assigned application number 09/248,674 and claim 8 of commonly assigned application number 09/248,673. The issue of priority under 35 U.S.C. 102(g) and

possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 13 of copending application Serial No. 09/240,557 and over Claims 1-8 of Serial No. 09/248,674 and over Claims 1-8 of Serial No. 09/248,673. Although the conflicting claims of said copending applications are not identical to those recited in the instant application, they are not patentably distinct from each other because the method of making a modified allergen and the compounds and compositions encompassed by the recited methods of the copending applications would be encompassed in the recitation of claims 1-13 of the instant application. This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-13 are directed to an invention not patentably distinct from claims 1-13 of copending application Serial No. 09/240,557 and over Claims 1-8 of Serial No. 09/248,674 and over Claims 1-8 of Serial No. 09/248,673, which are all commonly assigned applications.

These commonly assigned applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned cases qualify as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g).

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a method of making a modified allergen less reactive with IgE, wherein the modified allergen is based on protein from a wide range of plant, animal and organic species recited in claim 13 and encompassed by Claim 1. However, since the Applicants have not disclosed any specific protein from said species which has the properties of an allergen (other than the three Ara H peanut allergens), to which the recited method of modification of an allergen can be applied, the invention encompassing a method of modifying any allergen, other than the three Ara H peanut allergens, is not adequately described. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

15. Claim 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

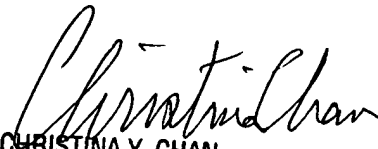
16. Claim 8 is indefinite in the recitation of "immune stimulatory sequences". The term on face value is broad, and it is therefore unclear exactly which immune stimulatory sequences the Applicants intend to claim. This rejection could be overcome by incorporating the definition of immune stimulatory sequences disclosed on page 7 into the claim.

17. No Claim is allowed, however claims 1-13 appear to be free of the prior art.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 10, 2000

  
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